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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,517	09/13/2001	Heidi Sue Dodson	020503-01-CA	2611

28880 7590 04/28/2003

WARNER-LAMBERT COMPANY
2800 PLYMOUTH RD
ANN ARBOR, MI 48105

EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
1651	J

DATE MAILED: 04/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/682,517	Applicant(s) Dodson et al.
	Examiner Ralph Gitomer	Art Unit 1651
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Feb 21, 2003</u> .		
2a) <input checked="" type="checkbox"/> This action is FINAL. 2b) <input type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>1-10</u> is/are pending in the application.		
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>1-10</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
*See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		
6) <input type="checkbox"/> Other: _____		

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The amendment received 2/21/2003 has been entered and claims 1-10 are currently pending in this application. The amended abstract is unacceptable because the sentences are incomplete and awkward.

In view of the amendments to the claims, the rejection of record of claims 1-10 under 35 USC 112, second paragraph, is hereby withdrawn.

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The objection to Fig. 3 is withdrawn in view of the information provided in the examples of the specification.

The rejection of record of claims 1-10 under 35 USC 112, first paragraph, is maintained.

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Applicant's arguments filed 2/21/2003 have been fully considered but they are not persuasive.

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Applicants argue that Example 1 and Fig. 3 are presented as a working example and results which enables the claims. Test compounds are commercially available and from them one would be able to identify dual substrate enzyme inhibitors. References are cited regarding controls.

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It is the examiner's position that the specification as originally filed fails to present any inhibitor found by the claimed method. No interpretable results are found in the file from the single assay described in the single Example. To state that test compounds are available does not enable a method to

determine WHICH of the test compounds meet certain desired characteristics. The references provided have not been made of record because they do not meet the requirements of an IDS and more importantly, do not substitute for adequate and proper written description in the specification.

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The rejection of record of claims 1-4, 8 under 35 USC 102(e) as being anticipated by Reynolds is maintained.

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Applicant's arguments filed 2/21/2003 have been fully considered but they are not persuasive.

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Applicants argue that Reynolds teaches assays in SPA format do not require washing steps and relies on the ligand binding to the support to bring the radioactive reacted product into scintillation proximity. The present claims require a separation step to remove unreacted radiolabeled second substrate from the reaction mixture. Further, Reynolds does not disclose two separate resins as required by the present invention which has both a capture resin and a scintillant resin.

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It is the examiner's position that Reynolds teaches in paragraph 40, the separation of the radioactive product from the radiolabeled substrate IS required if one does not employ SPA. This indicates other types of assays do require the separation. To mix and match steps from various types of assays for the known functions is well known in this art and no functions of any steps are presently claimed.

In paragraph 6 of Reynolds, a step is used to physically separate the radioactive product from the radiolabeled substrate. Then the radiolabeled product is quantitated by scintillation counting. In paragraph 41, the scintillant may be trapped in a different substrate than the one the ligand is bound to.

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An undisclosed advantage is given little or no weight.

The rejection of record of claims 5 and 6 under 35 USC 103(a) over the combination of Reynolds in view of Mathews and 10 Van Holde is maintained.

Applicant's arguments filed 2/21/2003 have been fully considered but they are not persuasive.

Applicants argue that there is no motivation to combine the references. Mathews does not make up for the deficiency of 15 Reynolds.

It is the examiner's position that Mathews was cited to teach specific enzymes, phosphate transfer enzymes, are key in fatty acid biosynthesis. Mathews teaches that fatty acid biosynthesis is controlled by kinases and phosphatases and 20 Reynolds is directed to fatty acid biosynthesis in general, see the abstract. The selection of specific enzymes well known in fatty acid synthesis would not appear critical the claimed invention which is merely directed to ~~identifying~~ an inhibitor of a dual substrate enzyme~~s~~. Reynolds is discussed above 25 regarding its relevance.

The rejection of record of claims 7, 9, and 10 under 35 USC 103(a) over the combination of Reynolds in view of Gul is maintained.

5 Applicant's arguments filed 2/21/2003 have been fully considered but they are not persuasive.

Applicants argue that Gul teaches that only one resin is used in a SPA assay. There is no suggestion in Reynolds or Gul to use a separation step or use a capture resin separately from a scintillant resin in a SPA. There is no motivation to modify 10 Reynolds for increasing sensitivity. Gul teaches that the SPA has the major advantage that the physical separation of product from substrate is not required. And Gul teaches away from the use of separate capture and scintillant resins.

It is the examiner's position that Gul clearly teaches the 15 separation of the product formed and the residual substrate. And Gul teaches it is preferable but not required to bind both the radiolabeled compound and the ligand to the same substrate. Regarding increasing sensitivity, such is a well known desirable characteristic of assays.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this 25 action. In the event a first reply is filed within TWO MONTHS of

the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee 5 pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If 15 attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist 20 whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing

Serial No. 09/682,517
Art Unit 1651

- 7 -

applications electronically, please visit our website at
www.uspto.gov and click on the button **Patent Electronic Business
Center** for more information.

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Ralph Gitomer

Ralph Gitomer
Primary Examiner
Group 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200